



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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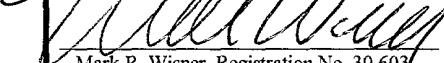
In Re Application of: § Atty Docket No.: PISA,007/C/CON
Madhavan Pisharodi §
Serial No.: Unknown § Prior Application:
§
Filed: April 13, 1999 § Serial No.: 08/900,174
§
Titled: **ROTATING, LOCKING** § Group Art Unit: 3738
INTERVERTEBRAL DISK §
STABILIZER AND § Examiner: P. Prebilic
APPLICATOR § Atty Docket No.: PISA,007/CIP

BOX PATENT APPLICATION
COMMISSIONER OF PATENTS
AND TRADEMARKS
WASHINGTON, D.C. 20231

CERTIFICATE OF MAIL BY EXPRESS MAIL

Express Mail Number: EJ318645821US
Date of Deposit: April 13, 1999

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.


Mark R. Wisner, Registration No. 30,603

April 13, 1999
Date of Signature

CONTINUATION APPLICATION

Sir:

This is a request for a filing under the continuation application procedure, 37 C.F.R. §1.60(b), of pending prior application Serial No. 08/900,174, filed on July 25, 1997, Madhavan Pisharodi, Inventor, for **ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER AND APPLICATOR**.

1. Enclosed is a complete copy of the prior application, including the oath originally filed and a statement verifying the enclosed papers as a true copy as set out below. The enclosed papers include:

- 10 pages of specification;
- 2 pages of claims;
- 1 page of abstract;
- 2 pages of drawings; and
- 2 pages of declaration executed by the inventor.

Please note that the prior application was itself a continuation-in-part application of prior application Serial No. 08/475,211, filed June 6, 1995 and entitled ROTATING, LOCKING, MIDDLE-EXPANDED INTERVERTEBRAL DISK STABILIZER (as amended). Serial No. 08/475,211 was a continuation-in-part of International Application No. PCT/US95/03347 entitled MIDDLE EXPANDED, REMOVABLE, INTERVERTEBRAL DISK IMPLANT AND METHOD OF LUMBAR INTERVERTEBRAL DISK STABILIZATION filed on March 17, 1995. International Application No. PCT/US95/03347 was itself a continuation-in-part of U.S. application Serial No. 08/210,229, filed March 18, 1994 and having that same title.

2. The filing fee is calculated on the basis of the claims existing in the prior application as amended at (5) below:

Basic Fee		\$760/\$380		
	Claims Paid For	Extra Claims	Fee	
Total Claims	20	- 0 -	\$18/ \$9	\$ - 0 -
Independent Claims	3	- 0 -	\$78/\$39	\$ - 0 -
TOTAL FEE DUE:				\$ - 0 -

3. A check in the amount of \$380.00 is enclosed. A copy of the Verified Statement of Small Entity Status filed with prior application Serial No. 08/900,174 is enclosed, as is a copy of the Verified Statement of Small Entity Status as filed in the prior application on behalf of the Assignee.

4. The Commissioner of Patents is hereby requested to credit any overpayment, or is authorized to draw on the Deposit Account of Payne, Lundeen, D'Ambrosio & Arismendi, L.L.P., Account No. 19-3884 (PISA,007/C/CON), if there the accompanying check is unsigned, is insufficient, or if the check is inadvertently not attached to this paper.

5. Cancel in this application original claims _____ inclusively of the prior application before calculating the filing fee. At least one independent claim has been retained for filing purposes.

6. Amend the specification by inserting before the first line the sentence --This application is a continuation application of co-pending application Serial No. 08/900,174, filed on July 25, 1997 and now issued as Patent No. 5,893,890--. All prior applications listed are hereby incorporated herein in their entirety by this specific reference.

7. The prior application Serial No. 08/900,174 was assigned to Perumala Corporation by Assignment executed November 17, 1998, which document was transmitted to the Office for recordation on December 28, 1998.

8. The power of attorney granted by the Inventor in the prior application is to:

Mark R. Wisner, Registration No. 30,603;
Alton W. Payne, Registration No. 30,580; and
Malcolm H. Skolnick, Registration No. 33,788.

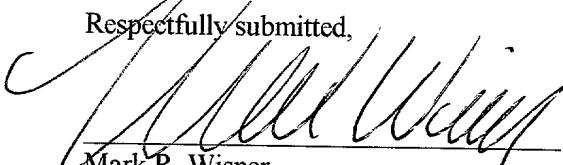
a. The power appears in the original papers in the prior application. A copy is enclosed for the convenience of the Office, as is the Power executed by the Assignee and filed in the prior application on December 28, 1998.

b. Address all future communications and telephone calls to:

Mark R. Wisner
Payne, Lundeen, D'Ambrosio & Arismendi, L.L.P.
1700 West Loop South, Suite 1230
Houston, Texas 77027-3008
(713) 840-8008
Facsimile: (713) 840-8088

9. I hereby certify that the attached papers are a true copy of prior application Serial No. 08/900,174, filed on July 25, 1997, and that no amendments referred to in the oath or declaration (if any) filed to complete the prior application introduced new matter therein.

Respectfully submitted,



Mark R. Wisner

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ATTORNEY FOR APPLICANT

Date: April 13, 1999

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File No. PISA,007/C/CON

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MALCOLM H. SKOLNICK, PH.D.
SHERMAN D. PERNIA, PH.D.
TIM W. CURINGTON

Commissioner of Patents and Trademarks
Washington, DC 20231

Re: Application of: Madhavan Pisharodi
Serial No.: 09/900,174
Filed: July 25, 1997
For: **ROTATING, LOCKING INTERVERTEBRAL DISK
STABILIZER AND APPLICATOR**

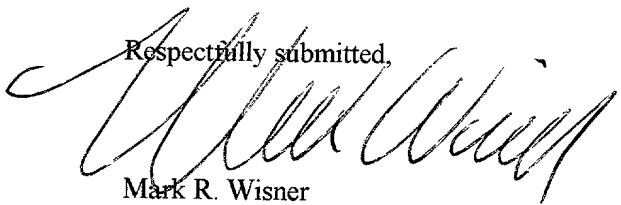
Dear Sir:

Enclosed for filing in connection with the captioned application is/are the following:

- Continuation Application under 37 C.F.R. §1.60(b); and
- Copy of pending prior application Serial No. 08/900,174 (including 10 pages of specification; 2 pages of claims; 1 page of abstract; 2 pages of Declaration; Power of Attorney; Verified Statement Claiming Small Entity Status.

Enclosed is our firm's check in the amount of \$380.00 to cover the fees in connection with this filing. The Commissioner of Patents is hereby authorized to draw on the Deposit Account of Sroufe, Payne & Lundein, L.L.P., Account No. 19-3884 (PISA,007/C/CON), if there are fees associated with this filing and/or if any required fees enclosed are insufficient, the check is unsigned, or if fees are inadvertently not enclosed. Please return the enclosed self-addressed, postage-prepaid postcard evidencing receipt of the above documents.

Respectfully submitted,


Mark R. Wisner
Attorney for Applicant
Registration No. 30,603

MRW/lm
Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:
Madhavan Pisharodi

Serial No.: Unknown

Filed: Concurrently Herewith

**Titled: ROTATING, LOCKING
INTERVERTEBRAL
DISK STABILIZER
AND APPLICATOR**

Atty. Docket No.: PISA,007/CIP

Examiner:

Group Art Unit:

COPY

BOX PATENT APPLICATION
COMMISSIONER OF PATENTS
AND TRADEMARKS
WASHINGTON, D.C. 20231

CERTIFICATE OF MAIL BY EXPRESS
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 Washington, D.C. 20231.

Mark R. Wisner
July 25, 1997
 Date of Signature

Mark R. Wisner, Registration No. 30,603

**VERIFIED STATEMENT (DECLARATION) CLAIMING
SMALL ENTITY STATUS (37 C.F.R. §§ 1.9(f) and 1.27(b))
INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. §1.9(c) for purposes of paying reduced fees under 35 U.S.C. §§41(a) and (b) to the Patent and Trademark Office with regard to the invention entitled **ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER AND APPLICATOR** described in the specification filed herewith.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. §1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. §1.9(d), or to a nonprofit organization under 37 C.F.R. §1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

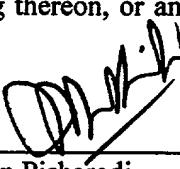
FULL NAME: _____
ADDRESS: _____

- INDIVIDUAL
- SMALL BUSINESS CONCERN
- NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 C.F.R. §1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date: July 24, 1997

Signature: 

Madhavan Pisharodi

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:
Madhavan Pisharodi

§ Atty. Docket No.: PISA,007/CIP
§
§

Serial No.: 08/900,174

§
§

Filed: July 25, 1997

§ Examiner: P. Prebilic
§

Titled: **ROTATING, LOCKING
INTERVERTEBRAL
DISK STABILIZER
AND APPLICATOR**

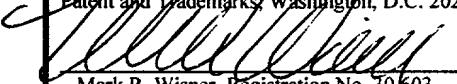
§ Group Art Unit: 3738
§
§

COPY

COMMISSIONER OF PATENTS
AND TRADEMARKS
WASHINGTON, D.C. 20231

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.

 Mark R. Wisner, Registration No. 30,603

Dec. 28, 1998

Date

**VERIFIED STATEMENT (DECLARATION) CLAIMING
SMALL ENTITY STATUS (37 C.F.R. §§1.9(f) and 1.27(c))
SMALL BUSINESS CONCERN**

I hereby declare that I am

the owner of the small business concern identified below
 an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Perumala Corporation
ADDRESS OF CONCERN: 942 Wild Rose Lane
Brownsville, Texas 78520

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. §121.1301 *et seq.* for purposes of paying reduced fees under 35 U.S.C. §§41(a) and 41(b), in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled **ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER AND APPLICATOR** by inventor Madhavan Pisharodi described in the above-identified patent application.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. §1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. §1.9(d) or a nonprofit organization under 37 C.F.R. §1.9(e).

FULL NAME: _____
ADDRESS: _____

INDIVIDUAL
 SMALL BUSINESS CONCERN
 NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. §1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.



SIGNATURE: _____
NAME OF PERSON SIGNING: Amayur P. Chandran
TITLE OF PERSON
(OTHER THAN OWNER): President
ADDRESS OF
PERSON SIGNING: 942 Wild Rose Lane
Brownsville, Texas 78520
DATE SIGNED: 11. 17 . , 1998

ROTATING, LOCKING INTERVERTEBRAL DISK STABILIZER AND APPLICATOR

5 CROSS REFERENCE TO RELATED APPLICATION

The present application is a continuation-in-part of co-pending application Serial No. 08/475,211, filed June 6, 1995 and entitled ROTATING, LOCKING, MIDDLE-EXPANDED INTERVERTEBRAL DISK STABILIZER (as amended). Serial No. 08/475,211 was a continuation-in-part of International Application No. PCT/US95/03347 10 entitled MIDDLE EXPANDED, REMOVABLE, INTERVERTEBRAL DISK IMPLANT AND METHOD OF LUMBAR INTERVERTEBRAL DISK STABILIZATION filed on March 17, 1995. International Application No. PCT/US95/03347 was itself a continuation-in-part of U.S. application Serial No. 08/210,229, filed March 18, 1994 and having that same title.

15 BACKGROUND OF THE INVENTION

The present invention relates to an intervertebral disk stabilizing implant for stabilizing two adjacent vertebrae. More specifically, the present invention relates to rectangularly-shaped disk implants which are expanded in the middle portion and are used for spinal fusion.

20 Treatment of a herniated disk in the neck and in the lumbar region continues to be a challenging field of medicine. The classical treatment for a ruptured disk is discectomy, i.e., removal of the disk from between the vertebrae. In this process, all or a portion of the intervertebral disk is removed, leaving a defect which continues to bother the patients throughout the rest of their lives. An additional procedure is to replace the 25 disk space with a bone graft, usually bone chips cut from the patient's iliac crest, bringing about fusion of the vertebrae above and below the disk, eliminating the empty space between the vertebrae.

30 Discectomy with fusion is not ideal because the replaced bone does not have the function of the cartilaginous tissue of the disk, i.e. no cushioning effect, and has complications because of several factors. First, conventional bone plugs used to pack the disk space do not conform to the space of the disk because the disk bulges maximally in the center. The disk space is wider in the middle and narrower at its anterior and

posterior ends. For this reason, the various bone plugs which are currently available commercially have only four contact points, i.e. at the front and back of the disk space. Secondly, access to the disk is from the side of the dorsal spine of the adjacent vertebrae, leaving a space that is "off-center" relative to the bodies of the adjacent vertebrae such 5 that the stability of the implant is even more problematical than might be apparent from the limited contact resulting from the shape of the intervertebral space. Another complication is the possibility of infection or other conditions which may require the removal of the implant. Also, if the bone pieces do not fuse, they may eventually extrude out of the disk space, causing pressure on the nerve roots.

10 Various prosthetic disk plugs, or implants, are disclosed in the art, but all are characterized by limitations of not conforming to the shape of the disk space, lack of stability when inserted off-center, inability to be removed, or other disadvantages. For instance, U.S. Patent No. 4,863,476 (and its European counterpart, EP-A-0260044) describes an elongated body divided longitudinally into two portions having a cam 15 device movable therebetween for increasing the space between the two body portions once inserted into the disk space. However, that device is generally cylindrical in shape such that the only contact points between the device and the vertebral bodies are at the front and back of the disk space, creating increased likelihood of instability and generally rendering that device unsuitable for use after partial disectomy. The art also discloses 20 intervertebral disk prostheses (e.g., U.S. Patent Nos. 3,867,728, 4,309,777, 4,863,477 and 4,932,969 and French Patent Application No. 8816184) which may have more general contact with the adjacent disks, but which are not intended for use in fusion of the disks. The art also includes spinal joint prostheses such as is described in U.S. Patent No. 25 4,759,769, which is again not indicated for use when fusion is the preferred surgical intervention.

There is, therefore, a need for a device capable of stabilizing the vertebrae adjacent an intervertebral disk, but which is also removable, for use in spinal fusion. There is also a need for a method of implanting such a stabilizer.

SUMMARY OF THE INVENTION

30 These needs are met in the present invention by providing a vertebral disk stabilizer comprising an elongate implant having first, second, third and fourth sides providing the implant with a substantially rectangular cross-sectional shape of minimal

height defined by the first and second sides and maximal width defined by the third and fourth sides, the third and fourth sides being arched from one end of the implant to the other to provide the portion intermediate the ends with a width larger than the width of the implant at the ends thereof. A lock having a bearing surface formed thereon is 5 detachably mounted to one end of the implant to prevent rotation of the lock relative to the implant with the bearing surface oriented at approximately 90° to the height of the implant.

A key is formed on the lock and a keyway is formed on the implant for receiving the key therein. The opening of the keyway is wider than the width of the key to 10 facilitate insertion of the key therein. The implant is inserted into the disk space with the implant oriented so that the first and second sides thereof engage the bodies of the adjacent vertebrae, rotated approximately 90° in the disk space so that the third and fourth sides contact the bodies of the adjacent vertebrae, and the lock is secured to the implant by inserting the key into the keyway to prevent rotation of the implant relative to 15 the lock. The bearing surface bears against the body of the adjacent vertebrae to prevent rotation of the lock relative to the body of the adjacent vertebrae against which the surface of the lock bears.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a lateral view of a portion of a human spinal column having a 20 preferred embodiment of vertebral disk stabilizer of the present invention inserted therein and having a portion of the bodies of the vertebrae adjacent the implant shown cut away and/or in shadow lines to show the engagement of the vertebral bodies by the vertebral disk stabilizer.

Figure 2 is an exploded, perspective view of the vertebral disk stabilizer of Fig. 1.

Figure 3 is a view of the implant of Fig. 1 and an applicator to which the implant 25 can be mounted in place of the lock shown in Fig. 2, the implant being shown in side, elevational view and the applicator being shown in top, plan view.

Figure 4 is an exploded, perspective view of a second preferred embodiment of the vertebral disk stabilizer of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures, a first embodiment of a disk stabilizer constructed in accordance with the teachings of the present invention is shown implanted in a human spinal column in Fig. 1. The vertebral disk stabilizer, indicated generally at reference 5 numeral 10, is implanted between the bodies 12 and 14 of two adjacent vertebrae 16 and 18, respectively, in the disk space (not numbered) from which a portion of the intervertebral disk 20 is removed, i.e. by simple discectomy and small laminotomy.

Referring now also to Fig. 2, the vertebral disk stabilizer 10 is comprised of an 10 elongate implant 22, lock 24, and means for detachably mounting the lock 24 to one end 25 of the implant 22. In the presently preferred embodiment shown, the mounting means takes the form of a bolt 26 passing through a bore 28 in lock 24, the threads of bolt 26 engaging complementary threads in the walls of the bore 30 in the end 25 of implant 22. A lock nut 31 may optionally be provided for resisting the loosening of the bolt 26 once lock 24 is mounted to lock 24 and implant 22 in the manner described below.

15 In more detail, implant 22 is comprised of first and second sides 32 and third and fourth sides 34 providing a substantially rectangularly shaped cross-section. The height H of the rectangularly shaped cross-section is defined by first and second sides 32 and the width W is defined by the third and fourth sides 34 and, as is apparent by comparison of H and W, the height of H of implant 22 is less than the width W. As will be explained 20 below, H is minimized to facilitate insertion of the second end 36 into, and positioning of implant 22 in, the disk space from which a portion of the intervertebral disk 20 was removed and W is maximized to provide the desired stabilization to adjacent vertebrae 16 and 18. Third and fourth sides 34 are arched from one end of implant 22 to the other to provide the portion of implant 22 intermediate the ends 25 and 36 with a width W which 25 is larger than the width W' and W" at the ends 25 and 36, respectively. By comparison of the widths at the ends and middle portions of implant 22, it can be seen that in the embodiment shown in Fig. 2, the width W' at the end 25 of implant 22 is less than the width W" at the end 36 of implant 22. Because the sides 32 of implant 22 are substantially flat and the sides 34 are arched from one end 25 to the other end 36, implant 30 22 is described as being a bi-planar, bi-convex implant. The bi-convex sides 34 of implant 22 are provided with a plurality of teeth 38 for biting into the adjacent vertebrae 16 and 18 as will be explained in more detail below. The end 36 of implant 22 is formed

in a blunt, or rounded shape to reduce the likelihood of injury to the nerves of the spinal cord during insertion into the disk space.

Those skilled in the art who have the benefit of this disclosure will recognize from the preceding paragraph that the sides 34 of implant 22 need not define an arch which is symmetrical from the end 25 to the end 36 of implant 22. It will also be recognized that the sides 34 of implant 22 need not be provided with the serrations 38 to bite into the adjacent vertebrae. This biting function can also be accomplished by providing the sides 34 with multiple steps formed in right angles from the narrowest portions at the ends 25 and 36 to the widest portion in the approximate middle of implant 22 (i.e., from the dimension W' to W to W").

In the preferred embodiment shown, lock 24 is substantially square when viewed from the end 40 along the axis of the bore 28 therethrough and U-shaped when viewed from the side. The inside surfaces 42 of the arms 44 of the U-shaped lock 24 are flat for contacting the first and second sides 32 of implant 22 to prevent rotation of lock 24 relative to implant 22 when lock 24 is mounted to implant 22 and secured thereto by bolt 26. The sides 32 of implant 22 are provided with a keyway 46 for receiving complementary-shaped keys 48 formed on the surfaces 42 of the arms 44 of lock 24 to facilitate assembly of lock 24 to implant 22; those skilled in the art who have the benefit of this disclosure will recognize that the keyway 46 may be located on the lock 24 and the key 48 may be located on implant 22 without any difference in the manner in which those component parts function. The mouth 45 of the keyway 46 on the side 32 of implant 22 at the first end 25 of the implant is wider than the width of the keyway 46 in the portion of the slot intermediate the ends 25 and 36 of implant 22 to facilitate insertion of the keys 48 of lock 24 into the keyway 46. The funnel-shaped portion 47 of the keyway 46 behind the mouth 45, which gradually decreases in width, acts to increase the ease with which lock 24 is mounted to implant 22 by insertion of the keys 48 into the respective keyways 46 and helps to seat lock 24 thereon and align the bore 28 in lock 24 with the bore 30 in implant 22.

The sides of the square end 40 of lock 24 provide surfaces 50 for bearing against the bodies 12 and 14 of adjacent vertebrae 16 and 18 as also explained in more detail below. It will be recognized by those skilled in the art who have the benefit of this disclosure that the bearing surfaces 50 need not be flat and that the end 40 of lock 24

need not be square. Other shapes and configurations may be utilized as needed to insure that movement of lock 24 is limited by the bodies of the adjacent vertebrae 16 and 18. The purpose of the bi-planar, middle expanded, bi-convex implant 22 is to enable insertion of the implant 22 into the disk space and turning by approximately 90° to 5 increase the disk height and stabilize the disk space. The purpose of lock 24 is to lock implant 22 against instability when in the vertical position so as to maintain the disk height thereafter.

Referring now to Fig. 3, an applicator for use in connection with the present invention is shown at 152 and is provided with an end 154 shaped in the form of a pair of 10 prongs 144. The prongs 144 are formed in a size and shape substantially identical to the size and shape of the arms 44 of lock 24. Applicator 152 is mounted to implant 22 by inserting the prongs 144 into the keyways 46 formed on the sides 32 of implant 22 (note that implant 22 must be rotated by 90° from the position shown in Fig. 3 to be mounted 15 on applicator 152, the implant 22 and applicator 152 being shown in the relationship shown in Fig. 3 to show the structure which enables the implant to be mounted to the applicator). In this manner, the prongs effectively function in the manner of the keys 48 formed on the surfaces 42 of the arms 44 of lock 24, seating the implant 22 on the end of applicator 152 and preventing relative rotational movement between implant 22 and applicator 152. Although not shown in the figure, those skilled in the art who have the 20 benefit of this disclosure will recognize that the end of the keyways 46 may be extended along the sides 32 of implant 22 further than is necessary to receive the keys 48 on lock 24 and that the extra length of the keyways 46 may be of gradually reducing dimension so that the prongs 144 of applicator 152 are received in a friction fit in the keyways 46 to 25 help affirmatively mount implant 22 thereto. Other structure for achieving this same result includes a detent or serrations formed in the keyways 46.

When the end 154 of applicator 152 is seated all the way into the keyways 46 of implant 22, so as to prevent relative rotational movement therebetween, implant 22 is inserted into the disk space and rotated therein using applicator 152 as explained below. Applicator 152 is then detached from implant 22 simply by withdrawing the applicator 30 152 from the disk space, the friction exerted by the adjacent vertebrae preventing the withdrawal of the implant 22. It will be apparent to those skilled in the art who have the benefit of this disclosure that the applicator 152 is of little assistance in removing the

implant 22 from the disk space even if the keyways 46 of implant 22 are provided with a detent or other structure to engage the prongs 144 of applicator 152 to retain the implant 22 thereon. In the event the implant 22 needs to be removed from the disk space, an applicator of the type shown in my prior, co-pending application Serial No. 08/475,211, 5 which disclosure is incorporated in its entirety as if fully set forth herein by this specific reference thereto, is screwed into the bore 30 to allow the implant 22 to be pulled from the disk space.

A second embodiment of the implant of the present invention is shown in Fig. 4. In this second embodiment, the structure corresponding to the structure of the 10 embodiment shown in Figs. 1-3 is designated with a prime to distinguish between the two embodiments. The arms 44' of lock 24' are shaped so that the arms 44' themselves provide the keys 48' which fit into the complementary-shaped keyways 46' on the surfaces 32' of implant 22'. Specifically, the arms 44' forming the U-shaped lock 24' are shaped in the form of prongs which fit into the keyways 46' of implant 22 in much the 15 same manner as described for the prongs 144 of the applicator 152 shown in Fig. 3. In this manner, the lock 24' functions in the same manner as the lock 24 of Figs. 1-3 to prevent rotation of implant 22' once inserted into the disk space and rotated by approximately 90°.

The use of the stabilizer 10 of the present invention in, for instance, a method of 20 lumbar intervertebral disk stabilization is illustrated in Fig. 1. Surgery is performed as in a simple discectomy and the intervertebral disk 20 is exposed through a small laminotomy. The disk material is removed and any nerve root compression is corrected. The posterior longitudinal ligament (not shown) and disk cartilage are removed until the 25 surface of the bodies 12 and 14 of adjacent vertebrae 16 and 18, respectively, are exposed above and below the disk space.

Using spreaders such as those disclosed in my International Application No. PCT/US95/00347, which reference is hereby incorporated into this specification in its entirety by this specific reference thereto, the vertebrae 16 and 18 are distracted to open the disk space, and once the desired "spread" is achieved, the middle portion of the disk 30 space is packed with cancellous bone chips (not shown). Because the posterior longitudinal ligament is left intact to the opposite side and to the center of the disk space, the bone chips are held in place in the disk space.

An implant 22 having a height H and width W selected to fit the disk space is then mounted to the prongs 144 of applicator 152. The appropriately-sized implant 22 is then inserted into the disk space using the applicator 152 with the implant 22 oriented so that the top and bottom thereof, i.e., the first and second sides 32, engage the bodies 12 and 14 of adjacent vertebrae 16 and 18, respectively. Using the applicator 152, implant 22 is positioned in the disk space at a position in which the expanded, middle portion and the smaller width ends 25 and 36 of the third and fourth sides 34 of implant 22 contact the respective lower and upper surfaces of the bodies 12 and 14 of the adjacent vertebrae 16 and 18 when rotated by approximately 90° using the applicator 152. The respective lower and upper surfaces of the vertebral bodies 12 and 14 are slightly concave such that the larger width middle portion W" of implant 22 allows the implant 22 to engage substantially more of the respective surfaces of the vertebral bodies 12 and 14 than conventional prosthetic devices, thereby providing increased stability to the fusion once further rotation of implant 22 in the disk space is prevented as described below.

Once positioned in the disk space so as to provide maximum stabilization, the applicator 152 is then detached from the implant 22 by backing out of the incision in the patient. Lock 24 is then inserted through that same incision and, using the slot 46 and key 48, the bore 28 in lock 24 and bore 30 in implant 22 are aligned and the bolt 26 is inserted and tightened to secure lock 24 to the implant 22. Securing the lock 24 to implant 22 in this manner prevents relative rotation between lock 24 and implant 22 and the bearing surfaces 50 of lock 24 bear against the bodies 12 and 14 of the adjacent vertebrae 16 and 18 to prevent rotation of the lock 24 relative to the adjacent vertebrae 16 and 18 against which the bearing surfaces 50 bear. Those skilled in the art who have the benefit of this disclosure will recognize that the bearing surfaces 50 bear against the cortical end plate of the respective vertebral bodies 12 and 14, which is comprised of non-cancellous bone, and provides a hard, relatively smooth surface against which the bearing surfaces 50 bear. The end 40 of lock 24 is preferably supplied in a plurality of different sizes and shapes other than the square shaped end 40 shown in the figures so as to allow the surgeon to select an appropriately sized and shaped lock which provides a close fit with the space between vertebral bodies.

If necessary, a small amount of a physiologically compatible adhesive of a type known in the art is applied over the cancellous bone chips just medial to the implant to

close off the remaining portion of the opening into the disk space. The patient should be able to ambulate soon after the procedure because of the stability imparted to the spinal column by the implant of the present invention. Before narrowing of the disk space occurs, the cancellous bone chips will have started the fusion process.

5 The stabilizer 10 is also used to advantage to perform, for instance, a posterior lateral intertransverse fusion. The implant 22 is inserted into the region of the disk space from which a portion of the disk has been removed as described above with the lock 24 and the posterior lateral fusion performed. Because the implant 22 provides stability to the spine until the posterior lateral fusion is solid, the patient is generally able to
10 ambulate soon after surgery. This procedure also prevents the narrowing of the disk space, which is a common problem with posterior lateral fusion.

Removal of the implant 22 is accomplished with relative ease compared to conventional implants. The bolt 26 is screwed back out of implant 22 and lock 24 is pulled out of the disk space. An applicator of the type described in the above-
15 incorporated Serial No. 08/475,211 is inserted into the disk space and screwed into the bore 30 in implant 22 and used to rotate implant 22 by approximately an additional 90°, causing the first and second sides, having minimal height, to contact the bodies 12 and 14 of adjacent vertebrae 16 and 18 so as to allow posteriorly-directed movement of the implant 22 out of the disk space.

20 Although described in terms of the preferred embodiment shown in the figures, this embodiment is shown to exemplify the present invention, it being recognized by those skilled in the art that certain changes can be made to the specific structure of the preferred embodiment shown and described without departing from the spirit of the present invention. In the case of one such change, the first and second sides of the
25 implant are substantially flat but not parallel along their longitudinal axes so that the implant is wedge-shaped. The wedge shape of the implant facilitates insertion of the implant into the disk space, the rounded end of the implant reducing the likelihood of injury to the nerves of the spinal cord during insertion into the disk space. Likewise, the width at one end of the implant can be less than the width at the end, both widths,
30 however, being less than the width in the middle, expanded portion of the implant. Further, the connection by which lock 24 is mounted to implant 22 is capable of being constructed in a manner different than that shown in the figures herein. Another such

implant into the disk space, the rounded end of the implant reducing the likelihood of injury to the nerves of the spinal cord during insertion into the disk space. Likewise, the width at one end of the implant can be less than the width at the end, both widths, however, being less than the width in the middle, expanded portion of the implant.

5 Further, the connection by which lock 24 is mounted to implant 22 is capable of being constructed in a manner different than that shown in the figures herein. Another such modification relates to the teeth 38 formed on the sides 34 of implant 22. So as to provide additional resistance to forward or backward movement of implant 22 in the disk space, the teeth 38 located closest to the end 25 of implant 22 (e.g., the teeth in the distal portion of implant 22) may be oriented at a slant toward the end 25 and the teeth 38 closest to the end 36 of implant 22 may be oriented at a slant toward the end 36. The teeth in the middle portion of implant 22, e.g., between the two sets of slanted teeth, are then oriented vertically. All such modifications, and other modifications which do not depart from the spirit of the present invention, are intended to fall within the scope of the

10

15 following claims.

WHAT IS CLAIMED IS:

1. A stabilizer for implanting in the disk space between adjacent vertebrae of a patient to stabilize the vertebrae comprising:

5 an elongate implant having a substantially rectangular cross-sectional shape with a minimal height defined by first and second sides and a maximal width defined by third and fourth sides, the third and fourth sides being arched from one end of the implant to the other;

a lock having a bearing surface formed thereon;

10 means for mounting said lock to one end of the implant to prevent rotation of the implant in the disk space when the implant is inserted into the disk space and rotated so that the third and fourth sides of the implant and the bearing surface of said lock contact the adjacent vertebrae;

a key formed on the lock; and

15 a keyway formed on said implant for receiving said key therein, said keyway having a mouth wider than the width of said key for facilitating insertion of said key therein.

2. The stabilizer of claim 1 wherein said keyway is provided with a funnel-shaped portion behind the mouth, the width of the funnel-shaped portion decreasing to the width of said keyway.

20 3. The stabilizer of claim 1 wherein both the first and second sides of the implant are provided with said keyways.

4. The stabilizer of claim 3 wherein said keyways are provided with funnel-shaped portions behind their respective mouths, the width of the funnel-shaped portions decreasing to the width of said keyways.

25 5. The stabilizer of claim 4 additionally comprising an applicator comprised of an elongate handle and a head, said head having a pair of prongs formed thereon shaped to fit into and engage the funnel-shaped portions of said keyways.

6. The stabilizer of claim 5 wherein the prongs of the head of said applicator are flush with the surfaces of the first and second sides of the implant when the prongs 30 are engaged to the funnel-shaped portions of said keyways.

7. The stabilizer of claim 1 additionally comprising a bolt for mounting said lock to the implant.

8. The stabilizer of claim 7 additionally comprising a lock nut for preventing the loosening of said lock nut.

ABSTRACT OF THE DISCLOSURE

A middle expanded, removable disk implant for stabilizing adjacent vertebrae. The implant is substantially rectangular in cross-sectional shape with a minimal height and a width greater than the height. The implant is detachably mounted to an applicator 5 for insertion into the anatomical region between two adjacent vertebrae from which a portion of the intervertebral disk has been removed. Once inserted, the implant is positioned by anterior-posterior movement in the disk space to the position in which both the expanded, larger width middle portion and the smaller diameter end portions of the implant engage the bodies of the adjacent vertebrae and the implant is then rotated to 10 bring the sides of the rectangularly-shaped implant defining the width of the implant, with its larger dimension, into engagement with the bodies of the adjacent vertebrae. A lock is then secured to the implant to prevent further rotation thereof.

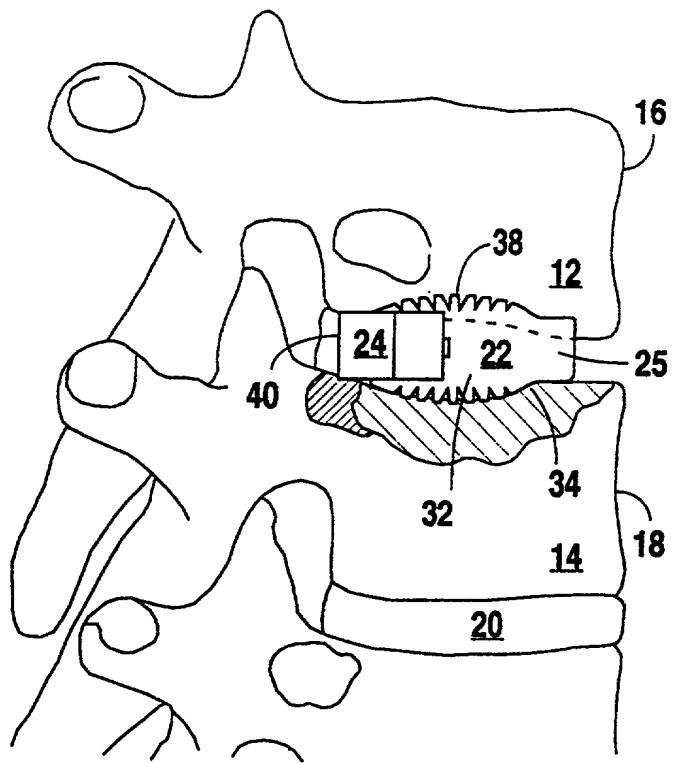
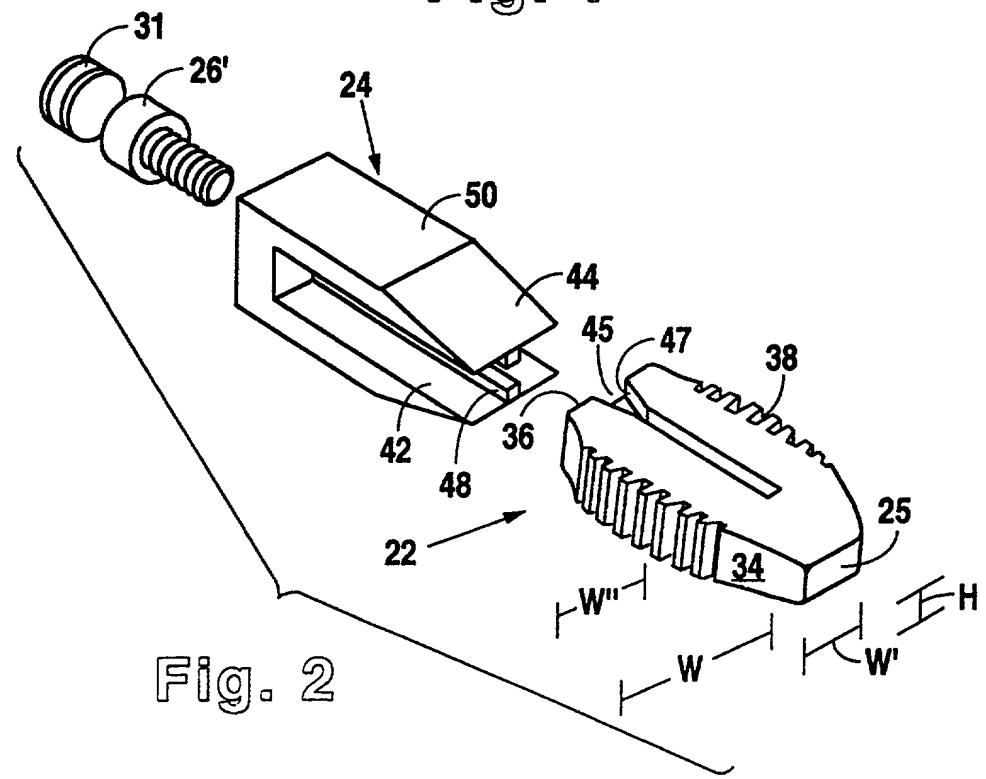


Fig. 1



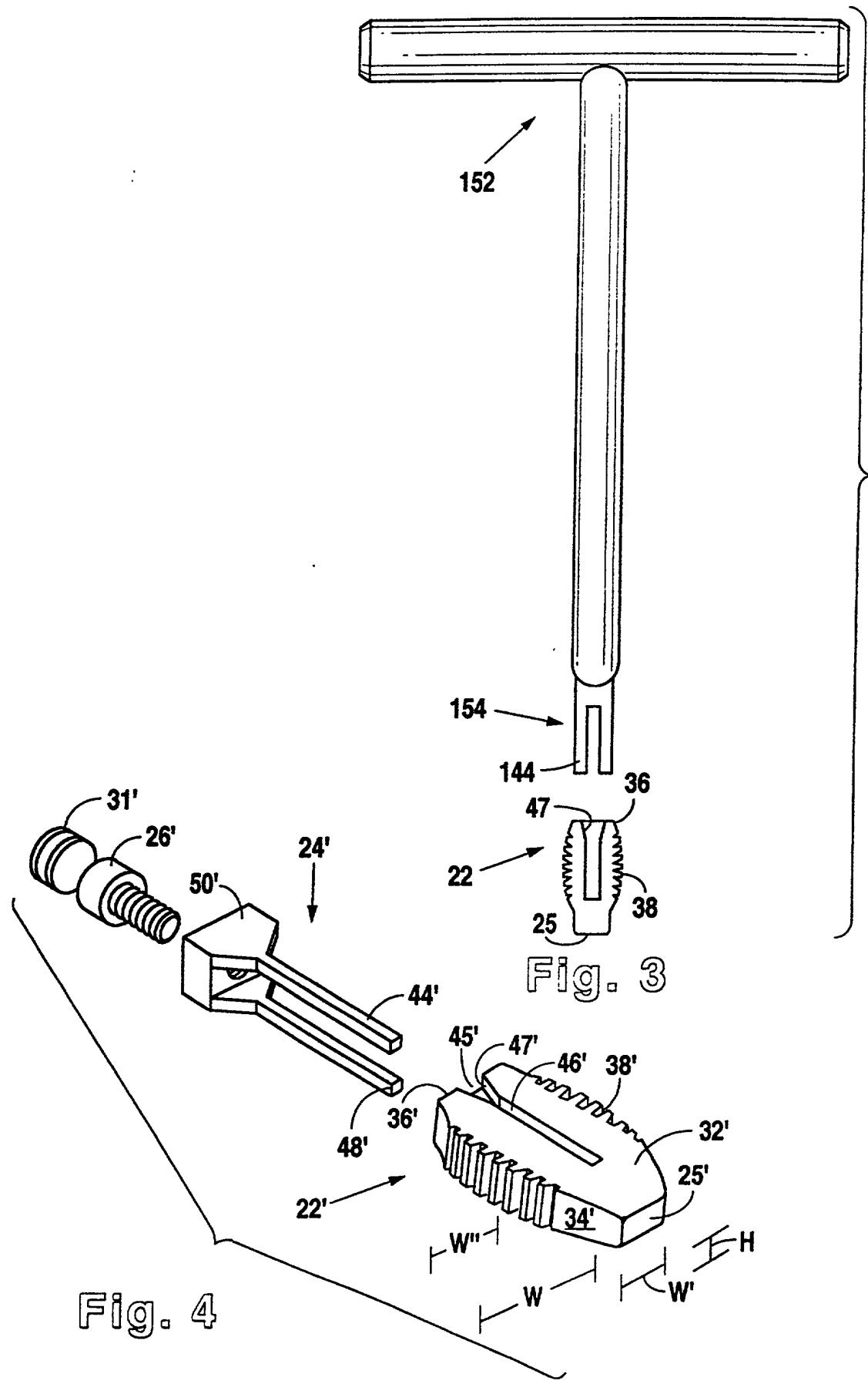


Fig. 4

Fig. 3

DECLARATION

COPY

As the below named inventor, I declare that:

My residence, post office address and citizenship are as stated below, next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**ROTATING, LOCKING INTERVERTEBRAL
DISK STABILIZER AND APPLICATOR**

the specification of which:

- is attached hereto.
- was filed on _____ as Application Serial No. _____ and with amendments through _____ (if applicable).
- was filed as PCT International Application No. PCT/____/____ on _____ and was amended under PCT Article 19 and/or PCT Article 34 before the International Preliminary Examining Authority.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

(Number)	(Country)	(Day, Month, Year)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>08/475,211</u> (Application Serial No.)	<u>June 6, 1995</u> (Filing Date)	<u>Pending</u> (Status: patented, pending, abandoned)
<u>PCT/US95/03347</u> (Application Serial No.)	<u>March 17, 1995</u> (Filing Date)	<u>Pending</u> (Status: patented, pending, abandoned)
<u>08/210,229</u> (Application Serial No.)	<u>March 18, 1994</u> (Filing Date)	<u>Pending</u> (Status: patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FULL NAME OF THE INVENTOR: Madhavan Pisharodi



INVENTOR'S SIGNATURE:

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CITIZENSHIP: United States

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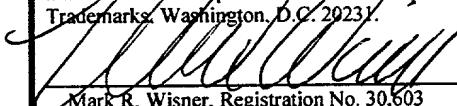
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of: § Atty. Docket No.: PISA,007/CIP
Madhavan Pisharodi §
§
§
Serial No.: 08/900,174 §
§
§
Filed: July 25, 1997 § Examiner: P. Prebilic
§
§
Titled: ROTATING, LOCKING § Group Art Unit: 3738
INTERVERTEBRAL §
DISK STABILIZER §
AND APPLICATOR §

COMMISSIONER OF PATENTS
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WASHINGTON, D.C. 20231

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patent and Trademarks, Washington, D.C. 20231.


Mark R. Wisner, Registration No. 30,603

Dec. 28, 1998
Date

POWER OF ATTORNEY AND ELECTION UNDER 37 C.F.R. § 3.71

Sir:

The undersigned, being the Assignee of the entire right, title and interest in the above-identified patent, hereby elects under 37 C.F.R. §3.71 to prosecute this patent to the exclusion of the inventor/previous assignee. In accordance with the provisions of 37 C.F.R. §3.73(b), attached hereto in the form of a Certificate Under 37 C.F.R. §3.73(b) executed by the Assignee is documentary evidence of a chain of title from the original owner to the Assignee or a specification by reel and frame number of where such evidence is recorded in the Patent and Trademark Office. Included in that Certificate is a statement specifying that the evidentiary documents have been reviewed and certifying that, to the best of Assignee's knowledge and belief, title is in the Assignee.

The Assignee hereby revokes any previous Power of Attorney and appoints:

Mark R. Wisner, Registration No. 30,603;

Alton W. Payne, Registration No. 30,580; and

Malcolm H. Skolnick, Registration No. 33,788;

jointly and severally, as Assignee's attorney or agent, with full power of substitution and revocation, to prosecute this patent, to make alterations and amendments therein, and to transact all business in the Patent and Trademark Office in connection therewith.

Please address all communications to:

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PERUMALA CORPORATION, Assignee

By: 

Signature of Corporate Officer

Typed/Printed Name: Amayur P. Chandran

Title: President

Date: 11.17, 1998

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:
Madhavan Pisharodi

§ Atty. Docket No.: PISA,007/CIP

Serial No.: Unknown

§

Filed: Concurrently Herewith

§

Examiner:

Titled: ROTATING, LOCKING
INTERVERTEBRAL
DISK STABILIZER
AND APPLICATOR

§

Group Art Unit:

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CERTIFICATE OF MAIL BY EXPRESS
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I hereby certify that this paper or fee is being deposited with the
United States Postal Service "Express Mail Post Office to
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and is addressed to the Commissioner of Patent and Trademarks,
Washington, D.C. 20231.

July 25, 1997
Mark R. Wisner, Registration No. 30,603 Date of Signature

POWER OF ATTORNEY

Dear Sir:

The undersigned inventor of the captioned application for Letters Patent hereby appoints Mark R. Wisner, Registration No. 30,603, Alton W. Payne, Registration No. 30,580, and Malcolm H. Skolnick, Registration No. 33,788, all members of the firm of Sroufe, Payne & Lundeen, L.L.P., his attorney to prosecute said application, and to transact all business in the Patent and Trademark Office connected therewith.

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Respectfully submitted,

Madhavan Pisharodi
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July 24, 1997

Date